
Chin K,1 Kim NH,2 Muros-Le Rouzic E,3 Brand M,3 Beyer A,3 Romero A,4 Channick RN,5 McLaughlin VV6

1UT Southwestern, Dallas, TX, USA; 2UC San Diego, La Jolla, CA, USA; 3Actelion Pharmaceuticals Ltd., Allschwil, Switzerland; 4Actelion Pharmaceuticals US, Inc., South San Francisco, CA, USA; 5Massachusetts General Hospital, Boston, MA, USA; 6University of Michigan, Ann Arbor, MI, USA

Background: Opsumit® (macitentan) is an FDA approved dual endothelin receptor antagonist (ERA) with sustained receptor binding indicated to delay disease progression in patients with pulmonary arterial hypertension (PAH). OPUS is a post-marketing requirement of the FDA to further characterize the safety profile, including potential hepatic risks, and to describe patient characteristics and clinical outcomes of patients newly treated with macitentan in the post-marketing setting.

Methods: The OPUS registry is a multi-center, long-term, prospective, longitudinal, real-world, observational, drug registry of new macitentan patients defined as therapy initiated ≤ 30 days prior to enrollment visit or at enrollment. All consecutive patients newly initiated on macitentan, seen at participating centers/clinics from university-affiliated or community hospitals, are invited to enroll in the study regardless of other PAH therapy received before or concomitant to enrollment, or during the study. Participation of physicians and patients in the study is on a voluntary basis. After providing informed consent, patients will be followed by their physician according to routine clinical practice for at least 1 year. The OPUS registry will not mandate any specific schedule of visits or investigations (i.e., monthly Liver Function Testing is not required). A secure, internet-based electronic data collection system will be used for data entry. OPUS will evaluate the following outcomes: occurrence of liver test abnormalities and other hepatic adverse events, occurrence of any other AEs, discontinuation of macitentan and reason for stopping therapy, hospitalization and death.

Conclusions: OPUS will be a unique observational, real-world registry, on the use of macitentan in the post-marketing setting and in clinical practice, enrolling a large and diverse population of patients newly treated with macitentan across the US.

Type: Clinical Science